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09/237,605 01/25/99 LAZZARA

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EXAMINER

PREBILIC, P

ART UNIT

PAPER NUMBER

3738

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/237,605

Applicant(s)
Lazzara et al

Examiner
Paul Prebilio

Art Unit
3738



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 14, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-50 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) ☐ Other: _____

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The two previously unconsidered articles have not been considered because copies thereof were provided. Enclosed is a copy of the relevant information disclosure statement showing that the Swiss patent and Branemark article have been initialed.

Specification

The attempt to incorporate subject matter into this application by reference to 08/607,903 is improper because it indicates that the present case was not complete as of the date of the provisional application (the grandparent application of the present case 60/009,592 was filed before the 08/607,903). Therefore, it is improper to still call the present application a continuation of 08/778,503 since the present disclosure is not identical to the parent or grandparent application.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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In particular, the declaration fails to set forth that the present application is a continuation-in-part of parent application 08/778,503. In addition, the declaration fails to set forth the grandparent application 08/351,204 even though Applicants rely on it.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-21 and 27-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology “substantially” or “substantially removed” to described the degree to which the native oxide layer is removed or the uniformity of the roughness lacks original support and/or there is no guidance as to its affect on the metes and bounds of the claim language. Since there is no guidance in the original specification, it appears that even a bulk etched metal implant surface would be substantially uniform in roughness and substantially free of the native oxide layer. Moreover, “substantially” is a broad term. *In re Nehrenberg*, 126 USPQ 383 (CCPA 1960) and see MPEP 2173.05(b) which is incorporated herein by reference. The specification fails to provide some standard for measuring that degree. Therefore, one of ordinary skill would not know what degree of roughness or native oxide layer

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would fall within the claim scope and what would not. The controlling case law appears to be that of *In re Mattison*, 184 USPQ 383 (CCPA 1960). It states:

We are not persuaded by the board's reasoning that one skilled in the art would not be able to determine the scope of the claimed invention in terms of a specified percentage value. General guidelines are disclosed for a proper choice of the substituent Ep together with a representative number of examples. (emphasis added here)

The Board of Appeals was reversed because there were general guidelines as to what constituted a substantial increase. This is not the situation here where there are no guidelines in the specification, and the prior art does not give one a clear picture as to what constitutes a substantially uniform roughness or a surface substantially free of native oxide and what does not. This is a critical and defining limitation of the claim and it must be clear as to what falls within its scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-21 and 27-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claims are indefinite because of the ambiguity presented by the "substantially" terminology discussed in the 35 USC 112, first paragraph rejection.

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Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16, 22-25, 27-33, and 35-49 are rejected under 35 U.S.C. 102(b) as anticipated by Krueger (US 4,826,434) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krueger (US 4,826,434) alone. Krueger anticipates the claim language wherein Krueger teaches a threaded surface intermediate product which has been etched to remove impurities; see the whole document, especially Figure 3 and Col. 3, line 38 to Col. 4, line 7. The Examiner asserts that at least one of the intermediate product (Col. 3, lines 50-56) and the final etched product would have their native oxide layers removed and would have irregularities of less than 10 microns approaching 0 microns; he therefore burden the Applicant to show otherwise. It is noted that the present claim language is now written in product-by-process format with two steps of treatment. Therefore, the Examiner is under a lesser burden of proof to show that these peculiar

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limitations are present in the prior art, but is under the position that the two step process would result in the same intermediate or final product due to the fact that it merely removes the oxide layer and smooths the outer surface. Consequently, the Examiner hereby asserts that the Krueger appears to be identical to the device set forth in the present claims; MPEP 2113 is hereby incorporated herein by reference thereto.

Alternatively, it is not clear that the intermediate product surface has a native oxide layer removed to the extent required, but the Examiner posits that the etching process, which increases the surface area by two, would obviously remove the native oxide layer to the extent claimed and the Examiner hereby burdens Applicant to show that the product disclosed by Krueger does not meet or obviate the claimed invention. Since the Office does not have facilities to test the prior art against the Applicant's invention, it is the Examiner prerogative to burden the Applicant to do the same when certain physical properties appear to be present in the prior art even though not explicitly taught thereby. In addition, since product-by-process claim language is now used, the Examiner asserts, under this interpretation, that the presently claimed invention is at least substantially identical to that set forth in Krueger.

With regard to claims 12, 25, 28, 38, 46, and 47, the Examiner posits that since the same type of etching process is used to form irregularities on the surface of the same material as claimed that the surface irregularities of Krueger would inherently be the same as those set forth in the claims; i.e. cone shaped.

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With regard to claims 13 and 36, the Examiner posits that the claimed process steps result in the same invention such that the claimed invention is at least clearly obvious in view thereof. The Examiner is also under a lesser burden to show that process limitations in product claims are met; see MPEP 2113 which is incorporated into this Office action by reference thereto.

Claims 26, 34, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger as applied to claims 11-16, 22-25, and 27-49 above, and further in view of Wagner et al (US 5,989,027). Krueger at least obviates the claim language as set forth in the above rejection but fails to teach both a roughened region and an unroughened or other region as required by the claims. Wagner et al teaches that it was known in the art to have different regions of roughness; see the entire document. Hence, it is the Examiner's position that it would have been obvious to have a smoother head portion in the Krueger invention for the same reasons that Wagner et al has the same.

Response to Arguments

Applicant's arguments filed February 14, 2001 have been fully considered but they are not persuasive.

In response to the Applicants' argument that the "substantially" objection should be withdrawn, it is the Examiner's position that since there is a lack of guidance in this regard, it would not be proper to withdraw the rejection. This is due to the fact that the case law is relatively clear as to what is required and the present disclosure falls short of that standard.

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Applicants argue that the teachings of Krueger are vague and they cannot see suggestion of the claimed invention; i.e. the reason Krueger etches his surface, they argue, is for a different reason and purpose. However, it is well established that anticipation is based upon a structure-to-structure comparison with the prior art. Since Krueger reasonably appears to have the same or similar structure as that set forth in the present claim language, the Examiner posits that the present claims are clearly unpatentable thereover. Moreover, the Examiner is under a lesser burden of proof when the claims are written in a product-by-process format because of their peculiar nature; see MPEP 2113.

As to the argument that it is not clear that Krueger has the claimed features of surface oxidation and roughness, the Examiner contends that the claim language is quite broad such that even Krueger's amount of detail anticipates or at least obviates it. Again, the claims must be viewed as a description of a product not by what steps they set forth. The method steps merely indicate what the final form of the invention might be.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.


Paul Prebilic
Primary Examiner
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